DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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June 4, 2002

WARNING LETTER NO. 2002-NOL-32

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Hung V. Huynh, President
Venice Seafood Exchange, Inc.
140 Tante-Phine Road
Venice, Louisiana 70091

Dear Mr. Huynh:

An investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your firm, located at 140 Tante-Phine Road, Venice, Louisiana, on March 13 and 15, 2002, and found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

- You must have a HACCP plan that lists the critical limits that must be met at each of the critical control points to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for Scombrotoxin species lists a critical limit at the "receiving" critical control point that is not adequate to control histamine formation in Scombrotoxin species. Please be aware that this deviation was brought to your attention previously in our letter dated September 10, 2001.

  As a primary processor, the critical limits for your receipt of fish from harvest vessels should ensure that all lots of fish are accompanied by harvest vessel records documenting the following: the fish were held at adequate temperatures while on board; a sensory examination of a representative sample of fish shows no more than 2.5% decomposition; and adequate post-mortem internal fish temperatures. For more detailed information, refer to Step #14: Set the Critical Limits, Chapter 7—Scombrotoxin (Histamine) Formation, of the Fish & Fisheries Products Hazards and Controls Guidance.

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur, and you must have and implement a written HACCP plan to control any of these food safety hazards to comply with 21 CFR 123.6(a) and 21 CFR 123.6(b). However, your firm does not have HACCP plans for Red Snapper, B-Liner (Snapper), Pompano, Trigger, and Amberjack fish to control the food safety hazard of ciguatera fish poisoning. For more information, refer to Chapter 6—Natural Toxins, in the *Fish & Fisheries Product Hazards & Controls Guide.*

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur, and you must have and implement a written HACCP plan to control any of these food safety hazards to comply with 21 CFR 123.6(a) and 21 CFR 123.6(b). However, your firm does not have HACCP plans for King Mackerel, Bluefish, and Amberjack to control the food safety hazard of histamine formation. For more information, refer to Chapter 7—Scombrotoxin (Histamine) Formation, in the *Fish & Fisheries Product Hazards & Controls Guide.*

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your revised HACCP plans and monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483